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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/079,819	05/15/98	ALVAREZ	V 1101209

EXAMINER

HM12/1103

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ART UNIT	PAPER NUMBER
1654	9

DATE MAILED: 11/03/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-97 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☐ Claim(s) _____ is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 1-97 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

(96)

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-21, 44 and 46-47, drawn to the protein, classified in class 530, subclass 350.

II. Claims 22-30, 40, 70, 73-74, 81-82 and 90-97 drawn to the composition , classified in class 424, subclass 185.1

III. Claims 31-39 and 75, drawn to a method of delivery, classified in class 424 , subclass 400.

IV. Claims 41 and 71, drawn to the chimerie protein , classified in class 530 , subclass 387.3 .

V. Claims 42, 43 and 45, drawn to the antibody, classified in class 530, subclass 387.

VI. Claims 48-69, 72 and 86-88, drawn to Recombinant Methods, classified in class 435, subclass 69.1.

VII. Claims 76-80, drawn to a method of testing or preventing disease, classified in class 514, subclass 12.

VIII. Claims 84, 85 and 89, drawn to assay methods, classified in class 436, subclass 86.

Inventions I and (III, VII and VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different

product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in an other materially different process of use such as an assay method, a pharmaceutically, a method of treatment of disease, a method of prevention of disease, or a method of delivery of the proteins.

The inventions are distinct, each from the other because of the following reasons: Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP§ 806.05(f)). In the instant case the product as claimed can be made by chemical synthesis, such as by the Merrifield method or by purification from natural sources by various chromatography techniques.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP §806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute apparently distinct inventions for the following reasons: the proteins of group I, the compositions of group II, the chimeric proteins of group IV and the antibodies of group V are chemically distinct products unrelated in sequence and separately classified having separate fields of search. The proteins of group I and the compositions of group II have no relationship to the antibodies of group V. The function and existence of either DNA or protein is not dependent on the existence of the other. The products of each group (I, II, IV or V) can be independently synthesized by chemical means. An antibody is encoded by an

entirely different DNA than that of the protein which is bound by that antibody, and the primary sequence of the antibody bears no relationship to the sequence of the detected protein. Each of the products have separate, unrelated to the sequence of the detected protein. Each of the products have separate, unrelated uses and are not disclosed as being capable of use together. Further, it would place burden on the examiner to examine several independent inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and the search for one group is not required for any other group, restriction for examination purposes as indicated is proper.

Claims 48-69, 72 and 86-88 are drawn to nucleotides, nucleotides constructs, and/or methods requiring the use if nucleotides or nucleotide constructs that contain more than ten individual, independent, and distinct nucleotide sequence in alternative form. Accordingly, these claims are subject to restriction under 35 USC § 121 as outlined in 1192 O.G. 68 (November 19, 1996).

Applicant is required to select no more that ten of the individual sequences for examination. The search of the no more than ten selected sequences may includes the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers). Note that any claim which is

amended or newly presented and recites specific cell clone, should recite both the clone number and the corresponding SEQ ID NO.

Upon election of Group I or II or IV Applicant is additionally required to elect a single protein or composition. This requirement is not to be construed as a requirement for an election of species, since each of the polypeptide recited in alternative form is not a member of a single genus of invention, but constitutes and independent and patentably distinct invention..

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143) Applicant is requested to provide a structure of the elected protein or a seq ID No. or the compositions components.

Applicants is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of a t least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37CFR 1.17(I).

Applicant is requested to match all proteins, polynucleotide with the corresponding sequence identifiers (SEQ. ID.NO:), in the claims and throughout the specification as required by 37CFR 1.821(d).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

A telephone call was made to Adriane Antler on September 25,1998 to request an oral election to the above restriction requirement, but did not result in an election being made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Avis Davenport whose telephone number is (703) 308-4002. The examiner can normally be reached on Tuesday-Friday from 8:30 am to 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward can be reached on (703) 308-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Avis M. Davenport

AVIS M. DAVENPORT
PRIMARY EXAMINER
GROUP 1800 1654